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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/741,664	12/21/2000	Ayoub Rashtchian	0942.3910003/RWE/BJD	7736

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WASHINGTON, DC 20005

EXAMINER

SITTON, JEHANNE SOUAYA

ART UNIT	PAPER NUMBER
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1634

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

09/741,664

Applicant(s)

RASHTCHIAN ET AL.

Examiner

Jehanne S. Sitton

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 1-2006.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application
- ☐ Other: _____.

DETAILED ACTION

1. Currently, claim 60 is pending in the instant application. All the amendments and arguments have been thoroughly reviewed but are deemed insufficient to place this application in condition for allowance. The following rejections are newly applied, as necessitated by amendment. They constitute the complete set being presently applied to the instant Application.

This action is FINAL.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. The rejection of claim 60, under 35 USC 112/2nd paragraph, made at section 5 of the previous office action regarding "storage" is withdrawn in view of the new grounds of rejection. The rejection with regard to the recitation of the term "then" is withdrawn in view of the arguments presented at page 3 of the response dated 1/25/2006.

4. The rejections of claim 60 under 35 USC 102(e), as anticipated by Gelfand and Hoelke, respectively, are withdrawn in view of the amendment to the claim to recite that the composition contain "at least one antibody that binds said thermostable polymerase".

Claim Rejections - 35 USC § 112

5. Claim 60 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim has been amended to recite “taking from storage at a temperature between -20°C to +4°C”. This recitation is indefinite as it is not clear if the temperature range is meant to signify the temperature at which the composition was stored, or the temperature at which the “taking from storage” is carried out.

Claim Rejections - 35 USC § 103

6. Claim 60 is rejected under 35 USC 103(a) as being unpatentable over Holmes (WO 95/00664) in view of Gelfand (US Patent 5,618,703), Hoeltke (US Patent 5,814,502), and Scalice (US Patent 5,338,671).

Holmes teaches methods of performing multiple PCR reactions using different primer pair and templates to identify primer pairs suitable for detection of Salmonella species in samples (see para bridging pages 2-3; page 7, first full para; page 14, last para). Holmes teaches that the PCR reactions contained 105 uL comprising template DNA, 50mMKCL, 2.5 mM MgCl₂ (instant claim 26), 10 mM Tris, 200uM each dNTP (instant claim 28), 0.5% Tween, and 2.5 units of Taq polymerase (23.8 U/ml). Holmes is silent with regard to the steps of making of the composition prior to template addition. Olson does not teach storage of the composition at a range of -20°C to +4°C or a PCR reaction mix containing an antibody that binds to the thermostable enzyme.

However, it was well known to those of ordinary skill in the art at the time the invention was made, that a master mix is typically employed when performing multiple reactions in order to improve efficiency and consistency and to avoid pipetting error. For example, Gelfand teaches methods of performing multiple reverse transcription reactions wherein all reagents are added in a master mix containing a thermostable polymerase, such as Taq, a nonionic detergent, all 4 dNTPs, and a buffer salt (see cols 27, 28, 30 and 31). Gelfand specifically teaches a method wherein multiple samples were analyzed and “for consistency and to avoid pipetting errors” the mix was prepared as a master mix and aliquoted as 17 uL into different reaction tubes such that only a single uL of primer and 2 uL of template were added (see col. 31). Further, Hoeltke specifically teaches making compositions containing pre-mixed reaction components in liquid form so that the user only has to add an aliquot of DNA in one single pipetting step (see col. 2, lines 20-22). Hoeltke teaches a composition which comprises a DNA polymerase, such as Taq, a buffering substance, a salt, and nucleoside triphosphates (see col 2, lines 32-50). Hoeltke teaches that these compositions exhibit particularly high stability when stored between -20 and 4 deg C. Scalice teaches that the use of an antibody specific for a thermostable DNA polymerase, such as Taq (cols 7-8), can be used to reduce or eliminate the formation of non specific products in PCR methods (see abstract).

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to improve the multiple PCR methods using different primers and template of Holmes with the use of a master mix, stored at a temperature between -20°C to +4°C, containing all reagents necessary for the reaction such that the methods could be performed requiring only contacting the PCR master mix with nucleic acid template and primers, as taught

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by Gelfand and Hoeltke. The ordinary artisan would have been motivated to provide a master mix for the purpose of improve the consistency and to reduce pipetting errors in the reactions of Holmes, as taught by Gelfand. The ordinary artisan would have been motivated to store such compositions at a temperature between -20°C to +4°C because Hoeltke teaches that such compositions exhibit particular high stability when stored between -20°C to +4°C. In performing the improved methods of Holmes in view of Gelfand and Hoeltke, it would have been further prima facie obvious to one of ordinary skill in the art at the time the invention was made to have made a composition that further included at least one antibody that binds said thermostable polymerase in view of the teachings of Scalice . The ordinary artisan would have been motivated to add an antibody specific for Taq polymerase to the PCR master mix of Holmes in view of Gelfand and Hoeltke for the purpose of reducing the formation of non specific PCR products in the methods of Holmes because Scalice teaches that such antibody can be used to reduce or eliminate the formation of non specific products in PCR methods. The ordinary artisan would have been motivated to add the antibody to the PCR master mixture of Holmes in view of Gelfand and Hoeltke for the purpose of providing necessary reagents in premixed form for use in any PCR reaction.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. No claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Sitton whose telephone number is (571) 272-0752. The examiner can normally be reached Monday-Thursday from 8:00 AM to 5:00 PM and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571) 272-0735. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Jehanne Sitton
Primary Examiner
Art Unit 1634

Jehanne Sitton
4/12/07